Article 34

WHAT IS CLAIMED IS:

1. A method for inhibiting bone resorption in a mammal, said method comprising orally administering to said mammal a pharmaceutically effective amount of a bisphosphonate as a unit dosage according to a continuous schedule having a dosing interval selected from the group consisting of once-weekly dosing, twice-weekly dosing, biweekly dosing, and twice-monthly dosing.

2. A method according to Claim 1 wherein said bisphosphonate is selected from the group consisting of alendronate, cimadronate, clodronate, tiludronate, etidronate, ibandronate, risedronate, piridronate, pamidronate, zolendronate, pharmaceutically acceptable salts thereof, and mixtures thereof.

3. A method according to Claim 1 wherein said bisphosphonate is selected from the group consisting of alendronate, pharmaceutically acceptable salts thereof, and mixtures thereof

4. A method according to Claim 3 wherein said pharmaceutically acceptable salt is alendronate monosodium trihydrate.

5. A method according to Claim 4 wherein said mammal is a human.

6. A method for treating osteoporosis in a mammal in need of such treatment, said method comprising orally administering to said mammal a pharmaceutically effective amount of a bisphosphonate as a unit dosage according to a continuous schedule having a dosing interval selected from the group consisting of once-weekly dosing, twice-weekly dosing, biweekly dosing, and twice-monthly dosing.

7. A method according to Claim 6 wherein said mammal is a human.

8. A method according to Claim 7 wherein said dosing interval is once-weekly and said unit dosage comprises about 70 mg of alendronate monosodium trihydrate, on an alendronic acid active basis.

9. A method according to Claim 7 wherein said dosing interval is twice-weekly and said unit dosage comprises about 35 mg of alendronate monosodium trihydrate, on an alendronic acid active basis.

10. A method according to Claim 7 wherein said dosing interval is biweekly and said unit dosage comprises about 140 mg of alendronate monosodium trihydrate, on an alendronic acid active basis.

11. A method according to Claim 7 wherein said dosing interval is twice-monthly and said unit dosage comprises about 140 mg of alendronate monosodium trihydrate, on an alendronic acid active basis.

12. A method for preventing osteoporosis in a mammal in need of such treatment, said method comprising orally administering to said mammal a pharmaceutically effective amount of a bisphosphonate as a unit dosage according to a continuous schedule having a dosing interval selected from the group consisting of once-weekly dosing, twice-weekly dosing, biweekly dosing, and twice-monthly dosing.

13. A method according to Claim 12 wherein said mammal is a human.

14. A method according to Claim 13 wherein said dosing interval is once-weekly and said unit dosage comprises about 35 mg of alendronate monosodium trihydrate, on an alendronic acid active basis.

15. A method according to Claim 13 wherein said dosing interval is twice-weekly and said unit dosage comprises about 17.5 mg of alendronate monosodium trihydrate, on an alendronic acid active basis.

16 A method according to Claim 13 wherein said dosing interval is biweekly and said unit dosage comprises about 70 mg of alendronate monosodium trihydrate, on an alendronic acid active basis.

17. A method according to Claim 13 wherein said dosing interval is twice-monthly and said unit dosage comprises about 70 mg of alendronate monosodium trihydrate, on alendronic acid active basis.

18. A method for inhibiting bone resorption in a mammal, said method comprising orally administering to said mammal a pharmaceutically effective amount of a bisphosphonate as a unit dosage according to a continuous schedule having a periodicity from about once every 3 days to about once every 16 days.

19. A method for treating osteoporosis in a mammal, said method comprising orally administering to said mammal a pharmaceutically effective amount of a bisphosphonate as a unit dosage according to a continuous schedule having a periodicity from about once every 3 days to about once every 16 days.

20. A method for preventing osteoporosis in a mammal, said method comprising orally administering to said mammal a pharmaceutically effective amount of a bisphosphonate as a unit dosage according to a continuous schedule having a periodicity from about once every 3 days to about once every 16 days.

21. A method according to any of Claims 1 - 20 wherein said unit dosage of said bisphosphonate comprises from about 1.5 to about 6000 $\mu$g/kg body weight.

22. A method according to any of Claims 1 - 20 wherein said unit dosage of said bisphosphonate comprises from about 10 to about 2000 $\mu$g/kg body weight.

23. A method for inhibiting bone resorption in a mammal comprising sequentially orally administering to said mammal a pharmaceutically effective amount of a unit dosage of a histamine H2 receptor blocker or a proton pump inhibitor and a unit dosage of a bisphosphonate according to a continuous schedule having a periodicity from about once every 3 days to about once every 16 days.



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24. A method for inhibiting bone resorption in a mammal comprising sequentially orally administering to said human a pharmaceutically effective amount of a unit dosage of a histamine H2 receptor blocker or a proton pump inhibitor and a unit dosage of a bisphosphonate according to a continuous schedule having a dosing interval selected from the group consisting of once-weekly dosing, twice-weekly dosing, biweekly dosing, and twice-monthly dosing.

25. A method according to Claim 24 wherein said histamine H2 receptor blocker or said proton pump inhibitor is administered from about 30 minutes to about 24 hours prior to the administration of said bisphosphonate.

26. A method according to Claim 24 wherein said bisphosphonate is selected from the group consisting of alendronate, cimadronate, clodronate, tiludronate, etidronate, ibandronate, risedronate, piridronate, pamidronate, zoledronate, pharmaceutically acceptable salts or esters thereof, and mixtures thereof.

27. A method according to any of Claims 23-26 wherein said histamine H2 receptor blocker or proton pump inhibitor is selected from the group consisting of cimetidine, famotidine, nizatidine, ranitidine, omeprazole, and lansoprazole.

28. A kit comprising, comprising:

(a) at least one pharmaceutically effective unit oral dosageof a bisphosphonate for oral administration, and

(b) at least one pharmaceutically effective unit dosage of a histamine H2 receptor blocker or a proton pump inhibitor.

29. A kit according to Claim 28 wherein said bisphosphonate is selected from the group consisting of alendronate, cimadronate, clodronate, tiludronate, etidronate, ibandronate, risedronate, piridronate, pamidronate, zoledronate, pharmaceutically acceptable salts or esters thereof, and mixtures thereof.



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30. A kit according to any of Claims 29 wherein said histamine H2 receptor blocker or proton pump inhibitor is selected from the group consisting of cimetidine, famotidine, nizatidine, ranitidine, omeprazole, and lansoprazole.

31. Use of a bisphosphonate for the manufacture of a medicament for inhibiting bone resorption in a mammal wherein said medicament is adapted for oral administration in a unit dosage form according to a continuous schedule having a periodicity from about once every 3 days to about once every 16 days.

32. Use of a bisphosphonate for the manufacture of a medicament for inhibiting bone resorption in a mammal wherein said medicament is adapted for oral administration in a unit dosage form according to a continuous schedule having a dosing interval selected from the group consisting of once-weekly dosing, twice-weekly dosing, biweekly dosing, and twice-monthly dosing.

33. Use of a bisphosphonate according to Claim 32 wherein said bisphosphonate is selected from the group consisting of alendronate, cimadronate, clodronate, tiludronate, etidronate, ibandronate, risedronate, piridronate, pamidronate, zoledronate, pharmaceutically acceptable salts thereof, and mixtures thereof.

34. Use of a bisphosphonate according to Claim 32 wherein said bisphosphonate is selected from the group consisting of alendronate, pharmaceutically acceptable sats thereof, and mixtures thereof.

35. Use of a bisphosphonate according to Claim 34 wherein said phamaceutically acceptable salt is alendronate monosodium trihydrate.

36. Use of a bisphosphonate according to Claim 35 wherein said mammal is a human.

37. Use of a bisphosphona[redacted] the manufacture of a medicament for [redacted] osteoporosis in a mammal in need thereof wherein said medicament is adapted for oral administration in a unit dosage form according to a continuous schedule [redacted]g a periodicity from about once every 3 days to about once every 16 days.

38. Use of a bisphosphonate for the manufacture of a medicament for treating osteoporosis in a mammal in need thereof wherein said medicament is adapted for oral administration in a unit dosage form according to a continuous schedule having a dosing interval selected from the group consisting of once-weekly dosing, twice-weekly dosing, biweekly dosing, and twice-monthly dosing.

39. Use of a bisphosphonate according to Claim 38 wherein said mammal is a human.

40. Use of a bisphosphonate according to Claim 39 wherein said dosing interval is once-weekly and said unit dosage comprises about 70 mg of alendronate monosodium trihydrate, on an alendronic acid active basis.

41. Use of a bisphosphonate according to Claim 39 wherein said dosing interval is twice-weekly and said unit dosage comprises about 35 mg of alendronate monosodium trihydrate, on an alendronic acid active basis.

42. Use of a bisphosphonate for the manufacture of a medicament for preventing osteoporosis in a mammal in need thereof wherein said medicament is adapted for oral administration in a unit dosage form according to a continuous schedule having a periodicity from about once every 3 days to about once every 16 days.

43. Use of a bisphosphonate for the manufacture of a medicament for preventing osteoporosis in a mammal in need thereof wherein said medicament is adapted for oral administration in a unit dosage form according to a continuous schedule having a dosing interval selected from the group consisting of once-weekly dosing, twice-weekly dosing, biweekly dosing, and twice-monthly dosing.

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37. Use of a bisphosphonate for the manufacture of a medicament for treating osteoporosis in a mammal in need thereof wherein said medicament is adapted for oral administration in a unit dosage form according to a continuous schedule having a periodicity from about once every 3 days to about once every 16 days.

38. Use of a bisphosphonate for the manufacture of a medicament for treating osteoporosis in a mammal in need thereof wherein said medicament is adapted for oral administration in a unit dosage form according to a continuous schedule having a dosing interval selected from the group consisting of once-weekly dosing, twice-weekly dosing, biweekly dosing, and twice-monthly dosing.

39. Use of a bisphosphonate according to Claim 38 wherein said mammal is a human.

40. Use of a bisphosphonate according to Claim 39 wherein said dosing interval is once-weekly and said unit dosage comprises about 70 mg of alendronate monosodium trihydrate, on an alendronic acid active basis.

41. Use of a bisphosphonate according to Claim 39 wherein said dosing interval is twice-weekly and said unit dosage comprises about 35 mg of alendronate monosodium trihydrate, on an alendronic acid active basis.

42. Use of a bisphosphonate for the manufacture of a medicament for preventing osteoporosis in a mammal in need thereof wherein said medicament is adapted for oral administration in a unit dosage form according to a continuous schedule having a periodicity from about once every 3 days to about once every 16 days.

43. Use of a bisphosphonate for the manufacture of a medicament for preventing osteoporosis in a mammal in need thereof wherein said medicament is adapted for oral administration in a unit dosage form according to a continuous schedule having a dosing interval selected from the group consisting of once-weekly dosing, twice-weekly dosing, biweekly dosing, and twice-monthly dosing.

44. Use of a bisphosphonate according to Claim 43 wherein said [redacted]mal is a human.

45. Use of a bisphosphonate according to Claim 44 wherein said dosing interval is once-weekly and said unit dosage comprises about 35 mg of alendronate monosodium trihydrate, on an alendronic acid active basis.

46. Use of the combination of a bisphosphonate and a histamine H2 receptor blocker or a proton pump inhibitor for the manufacture of a medicament for inhibiting bone resorption in a mammal comprising sequentially orally administering to said mammal a pharmaceutically effective amount of a unit dosage of a histamine H2 receptor blocker or a proton pump inhibitor and a unit dosage of a bisphosphonate according to a continuous schedule having a periodocity from about once every 3 days to about once every 16 days

47. Use of the combination of a bisphosphonate and a histamine H2 receptor blocker or a proton pump inhibitor for the manufacture of a medicament for inhibiting bone resorption in a mammal comprising sequentially orally administering to said mammal a pharmaceutically effective amount of a unit dosage of a histamine H2 receptor blocker or a proton pump inhibitor and a unit dosage of a bisphosphonate according to a continuous schedule having a dosing interval selected from the group consisting of once-weekly dosing, twice-weekly dosing, biweekly dosing, and twice-monthly dosing.

48. A pharmaceutical kit useful for inhibiting bone resorption in a mammal comprising at least one pharmaceutically effective unit dosage of a bisphosphonate for oral administration according to a continuous schedule characterized in that

(a) said unit dosage of said bisphosphonate comprises about 70 mg, on an alendronic acid active basis, of a bisphosphonate selected from the group consisting of alendronate, pharmaceutically acceptable salts or esters thereof, and mixtures thereof,

(b) said continuous schedule is once-weekly, and

(c) said kit comprises a memory aid for administering said unit dosages.



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49. A pharmaceutical kit according to claim 48 wherein said unit dosages are oriented in said pharmaceutical kit in the order of their intended use.

50. A pharmaceutical kit according to claim 49 wherein said memory aid indicates that said unit dosage is administered once a week.

51. A pharmaceutical kit according to claim 50 wherein said memory aid indicates a unit dosage is administered on each of week 1, week 2, week 3, and week 4

52. A pharmaceutical kit according to claim 51 wherein said memory aid indicates that said unit dosage is administered once during a seven day period.

add A3

add B2

add C1